SECTION 5 – 510(K) SUMMARY

MAY 1 3 2014

Submitted by: Biomet Trauma
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Contact Person: Suzana Otaño, Regulatory Affairs Manager

Date Prepared: May 7, 2014

Proprietary Name: Dorsal, Lateral and Ulna Plating System

Common Name: Plate, Fixation, Bone

Classification Name / Product Code: Single/multiple component metallic bone fixation appliances and accessories (21 CFR § 888.3030) / HRS

Predicate Devices: The Dorsal, Lateral and Ulna Plating System is substantially equivalent to the currently marketed Small Bone Locking Plating System (K081546, K083364) and Distal Volar Radius Plating System (K112345).

Device Description: The Dorsal, Lateral and Ulna Plating System consists of Titanium alloy plates utilizing non-locking, locking and variable angle screws manufactured from Titanium alloy and CoCr for bone fixation and the management of fractures, revisions, fusions and reconstructive surgeries. They can be provided in a pre-packaged sterile kit with accompanying single use instrumentation, individually packaged sterile units or non-sterile for further steam sterilization prior to use. Offered in left and right configurations, with the exception of the Ulna plate that is bilateral, the plates are for use with existing 2.2mm pegs and 2.7mm locking and non-locking screws and multidirectional fasteners.

Indications for Use: The system is intended for stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstructions (osteotomies) of small bones of the hand, foot, radius, ulna, ankle, humerus, scapula and pelvis, particularly in osteopenic bone.

Technological Characteristics:	The technological characteristics of the Dorsal, Lateral and Ulna Plating System are similar to the predicate devices including design, dimensions and material.
Summary of Substantial Equivalence:	The Dorsal, Lateral and Ulna Plating System is substantially equivalent to currently marketed devices as demonstrated with pre-clinical data including axial load construct testing, evaluation of galvanic corrosion potential and multidirectional screw capability. No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 13, 2014

Biomet Manufacturing Corporation
Ms. Suzana Otaño
Regulatory Affairs Manager
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581

Re: K140622
Trade/Device Name: Dorsal, Lateral and Ulna Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: March 19, 2014
Received: March 20, 2014

Dear Ms. Otaño:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE STATEMENT

510(k) Number: K140622

Device Name: **Dorsal, Lateral and Ulna Plating System**

Indications For Use:

The system is intended for stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstructions (osteotomies) of small bones of the hand, foot, radius, ulna, ankle, humerus, scapula and pelvis, particularly in osteopenic bone.

Prescription Use X AND/OR Over-the-Counter _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Frank -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K140622